UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF TENNESSEE

MARY ANN KELLEHAR,

individually, as surviving spouse, and on behalf of the estate of Cornelius Kellehar,

Plaintiff,

vs.

XANODYNE PHARMACEUTICALS, INC.,

Defendant.

Civil Action No.

COMPLAINT

Jury Demand Requested

Plaintiff, by and through undersigned counsel, respectfully represents that he had injuries and incurred damages arising out of the use of the drugs Darvon and Darvocet. In support of his Complaint, Plaintiff alleges as follows:

NATURE OF THE CASE

1. This is an action for damages suffered by Cornelius Kellehar, including sudden death, as a direct and proximate result of Defendant's wrongful conduct in connection with the development, design, manufacture, distribution, and selling of Defendant's prescription pain medications Darvon and Darvocet.

2. Defendant knew or should have known that Darvon and Darvocet, when taken as prescribed and intended, causes and contributes to a greatly increased risk of serious and dangerous side effects including, without limitation, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death. Further, Defendant marketed the

widespread use of Darvon and Darvocet while withholding adequate warnings of the drugs' dangerous side effects and that Darvon and Darvocet were unreasonably unsafe.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (diversity jurisdiction) because the amount in controversy exceeds $75,000.00 exclusive of interest and costs, and because this is an action by Plaintiff who is a citizen of a different state from the Defendant.

4. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

5. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiff's claims occurred in this District.

PARTIES

6. Plaintiff Cornelius Kellehar ("Plaintiff") was domiciled in Millington, TN at the time of his death on November 2, 2010. Plaintiff Mary Ann Kellehar is the widow of Plaintiff and entitled to bring this action under Tennessee law.

7. Plaintiff was prescribed and purchased the drug Darvon for pain management on or about July 30, 2010 and continued the use of the drug Darvon up to and on the date of his death.

8. Plaintiff was prescribed and purchased the drug Darvocet for pain management prior to July 30, 2010.

9. As a result of using the drugs Darvon and Darvocet, Plaintiff suffered sudden cardiac death on November 2, 2010.

10. Upon information and belief, Defendant Xanodyne Pharmaceuticals, Inc. ("Defendant"), was at all relevant times a Kentucky corporation with its principal place of business located in Kentucky.

11. Upon information and belief, at all relevant times Defendant has transacted and conducted business in the State of Tennessee and derived substantial revenue from interstate commerce.

12. Upon information and belief, Defendant describes itself as an integrated specialty pharmaceutical company with both development and commercial capabilities focused on pain management.

13. Upon information and belief, Defendant was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute Darvon for use as a prescription management medication.

14. Upon information and belief, Defendant was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute Darvocet for use as prescription management medications.

FACTUAL BACKGROUND

15. This action is brought on behalf of Plaintiff who was prescribed, purchased and correctly used Darvon and Darvocet.

16. At all material times, Defendant, either themselves or by use of others, manufactured, created, designed, tested, sterilized, packaged, distributed, supplied, marketed, sold, advertised, warned, and otherwise distributed in interstate commerce the drugs Darvon and Darvocet.

17. The FDA first approved propoxyphene, the primary drug in Darvon and Darvocet, for distribution in 1957.

18. According to the FDA, about 10 million people in 2009 received prescriptions for propoxyphene related drugs.

19. Darvon, when taken as prescribed and intended, causes and contributes to a greatly increased risk of serious and dangerous side effects including, without limitation, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

20. Darvocet, when taken as prescribed and intended, causes and contributes to a greatly increased risk of serious and dangerous side effects including, without limitation, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

21. Defendant concealed its knowledge of Darvon's and Darvocet's defects from plaintiff, the U.S. Food and Drug Administration ("FDA"), the public in general, and the medical community specifically.

22. Defendant extensively marketed the drugs Darvon and Darvocet to induce its widespread use. Upon information and belief, Adverse Event data maintained by the FDA

indicates staggering, serious Adverse Events, including, heart arrhythmias, atrial fibrillation, tachycardia, bradycardia, myocardial infarction, and/or sudden death as a result of the use of Darvon and Darvocet.

23. In June 2009, the European Medicines Agency ("EMEA") recommended that marketing authorizations for propoxyphene be withdrawn across the European Union for safety concerns.

24. In 2009, the FDA Advisory Committee voted against the continued marketing of propoxyphene products such as Darvon and Darvocet. Despite the Advisory Committee's recommendation, the FDA allowed Darvon, Darvocet and other propoxyphene related drugs to remain on the market but ordered a safety study assessing unanswered questions about the effects of Darvon and Darvocet on the heart.

25. A study conducted by Defendant indicated that even when taken at recommended doses, propoxyphene causes significant changes to the electrical activity of the heart. These changes, which can be seen on an electrocardiogram (ECG), can increase the risk for serious abnormal heart rhythms that have been linked to serious adverse effects, including sudden death.

26. On November 19, 2010, the FDA announced that Defendant had agreed to halt all U.S. marketing of Darvon and Darvocet after it was determined that the drug's benefits were outweighed by the risks associated with its use, specifically the potential of the drugs to cause serious and potentially fatal heart arrhythmias.

27. Defendant did not provide adequate warnings to Plaintiff or the medical community about the increase risk of serious adverse events that are described herein.

28. As a result of Plaintiff's correct use of Darvon and Darvocet, Plaintiff sustained damages including, but not limited to, atrial fibrillation leading to sudden death.

29. On information and belief, Defendant violated or failed to comply with numerous federal requirements and/or regulations in the manufacture, design, sale, and distribution of Darvon and Darvocet.

30. Defendant failed to meet the applicable standard of care governing the manufacture, design, sale, and distribution of Darvon and Darvocet.

31. By reason of the foregoing, Defendant is liable to Plaintiff under the theories of negligence, strict product liability and breach of implied warranties.

FIRST CAUSE OF ACTION
Negligence

32. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

33. At all relevant times, Defendant had a duty to exercise reasonable care in the design, sale, and distribution of Darvon and Darvocet, including a duty to ensure that Darvon and Darvocet did not pose a significantly increased risk of bodily injury to its users.

34. Defendant had a duty to exercise reasonable care in the advertising and sale of Darvon and Darvocet, including a duty to warn Plaintiff and the medical community, of the dangers associated with the consumption of Darvon or Darvocet that were known or should have been known to Defendant at the time of the sale of Darvon and Darvocet to Plaintiff.

35. Defendant failed to exercise reasonable care in the design, sale, and distribution of Darvon and Darvocet because Defendant knew or should have known that Darvon and Darvocet had a propensity to cause serious injury, including without limitation, heart arrhythmias, myocardial infarction, other adverse cardiovascular events, and/or sudden death.

36. Defendant failed to exercise ordinary care in the labeling of Darvon and Darvocet and failed to issue adequate pre-marketing or post-marketing warnings to prescribing doctors and

the general public regarding the risk of serious injury, including, without limitation, , heart arrhythmias, myocardial infarction, other adverse cardiovascular events, and/or sudden death.

37. Darvon and Darvocet as designed, sold, and distributed by Defendant reached Plaintiff without substantial change in its condition and were used by Plaintiff in a reasonably foreseeable and intended manner.

38. Defendant knew or should have known that Plaintiff could foreseeably suffer injury as a result of Defendant's failure to exercise ordinary care as described above.

39. Defendant breached its duty of reasonable care to Plaintiff by failing to exercise due care under the circumstances.

40. As a direct and proximate result of Defendant's acts and omissions, including its failure to exercise ordinary care in the design, sale, distribution, and failure to warn of the risks and dangers of Darvon and Darvocet, Plaintiff ingested Darvon and Darvocet and suffered severe injuries including atrial fibrillation and sudden cardiac death. Therefore, Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SECOND CAUSE OF ACTION
Strict Product Liability

41. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

42. At all relevant times hereto, Defendant was engaged in the development, testing, manufacturing, marketing and sales of Darvon and Darvocet. Defendant designed, manufactured, marketed, and sold Darvon and Darvocet to medical professionals and its patients, knowing it would be ingested as a prescription pain medication.

43. Darvon and Darvocet as designed, manufactured, marketed and sold by Defendant reached Plaintiff without substantial change in its condition and were used by Plaintiff in a reasonably foreseeable and intended manner.

44. Darvon and Darvocet were "defective" and "unreasonably dangerous" when it entered the stream of commerce and was received by Plaintiff, because they were dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that Darvon and Darvocet were in a condition not suitable for their proper and intended use among patients.

45. Darvon and Darvocet were used in the manner for which it was intended, that is, for use as a pain medication. This use resulted in injury and death to Plaintiff.

46. Plaintiff was not able to discover, nor could he have discovered through the exercise of reasonable care, the defective nature of Darvon and Darvocet. Further, in no way could Plaintiff have known that Defendant had designed, developed, and manufactured Darvon and Darvocet in such a way as to increase the risk of harm or injury to the recipients of Darvon and Darvocet.

47. Darvon and Darvocet are defective in design because of its propensity to cause, without limitation, heart arrhythmias, myocardial infarction, other adverse cardiovascular events, and/or sudden death.

48. Darvon and Darvocet is unreasonably dangerous because it was sold to Plaintiff without adequate warnings regarding the propensity to cause, without limitation, heart arrhythmias, myocardial infarction, other adverse cardiovascular events, and/or sudden death.

49. Defendant failed to develop and make available alternative products that were designed in a safe or safer manner, even though such products were feasible and marketable at the time Defendant sold Darvon and Darvocet to Plaintiff.

50. Defendant had knowledge and information confirming the defective and dangerous nature of Darvon and Darvocet. Despite this knowledge and information, Defendant failed to adequately and sufficiently warn Plaintiff and his physicians that Darvon and Darvocet causes serious heart arrhythmias, myocardial infarction, other adverse cardiovascular events, and/or sudden death.

51. As a direct and proximate result of Defendant's wrongful conduct, including Darvon's and Darvocet's defective and dangerous design and inadequate warnings, Plaintiff sustained injuries including atrial fibrillation and sudden cardiac death. Therefore, Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

THIRD CAUSE OF ACTION
Breach of Implied Warranties

52. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

53. Defendant designed, marketed, sold, and distributed Darvon and Darvocet as has previously been alleged and described herein.

54. At the time Defendant marketed, sold and distributed Darvon and Darvocet, Defendant knew of the use for which Darvon and Darvocet were intended and impliedly warranted that Darvon and Darvocet were merchantable, safe and fit for its intended purpose: namely that Plaintiff could ingest Darvon and Darvocet without the risk of serious injury.

55. Plaintiff, foreseeable user of Darvon and Darvocet, and Plaintiff's physician(s), reasonably relied upon Defendant's judgment and implied warranties in purchasing and consuming Darvon and Darvocet as intended.

56. Darvon and Darvocet were defective, unmerchantable, and unfit for ordinary use when sold, and subjected Plaintiff to severe injuries.

57. Defendant breached its implied warranties because Darvon and Darvocet were neither of merchantable quality nor safe for their intended use in that Darvon and Darvocet have the propensity to cause, without limitation, heart arrhythmias, myocardial infarction, other adverse cardiovascular events, and/or sudden death.

58. As a direct and proximate result of Defendant's breach of the implied warranties of merchantability and fitness for its intended purpose, Plaintiff ingested Darvon and Darvocet and suffered sustained injuries including atrial fibrillation and sudden cardiac death. Therefore, Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendant as follows:

1. Economic and non-economic damages in an amount in excess of $75,000 as provided by law and to be supported by the evidence at trial;

2. For equitable relief requested;

3. For compensatory damages according to proof;

4. For all statutory damages under the applicable consumer protection legislation;

5. For disgorgement of profits;

6. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of Defendant who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to Plaintiff in an amount sufficient to punish Defendant and deter future similar conduct;

7. For an award of attorneys' fees and costs;

8. For prejudgment interest and the costs of suit; and

9. For such other and further relief as this Court deems just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury in this case as to all claims in this action.

Dated: 01/13/11 Respectfully Submitted,

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